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TAGS: CD PARM PREL BWC CWC CBW TBIO

SUBJECT: PART ONE OF TWO -- BIOLOGICAL WEAPONS CONVENTION:
DETAILED READ-OUT OF EXPERTS GROUP MEETING ON BIOSAFETY,
BIOSECURITY AND PROFESSIONAL RESPONSIBILITY IN THE LIFE
SCIENCES, AUGUST 18-22, 2008

REF: REF A: STATE 088219 REF B: GENEVA 719

Begining of text of part one of two.

¶1. (U) This cable is sensitive but unclassified and should be protected accordingly.

¶2. (SBU) Summary. The second annual meeting of BWC Experts for the 2007-2010 Work Program, focusing on biosafety, biosecurity, and professional responsibility in the life sciences, marked progress, registered gaps, and shared ideas on how to move the issues forward. The meeting was notable for the active participation in most sessions not only by States Parties, but by Observer States, Intergovernmental Organizations, professional associations, industry representatives, scientific bodies, and others from the private sector and civil society. This engagement reflected a recognition among States Parties that the ability to counter the BW threat is enhanced by the active involvement of a coalition of those with interest in implementing the actions discussed in BWC fora.

¶3. (SBU) There has been significant progress on biosafety and biosecurity since the BWC held its initial meeting on the subject in 2003, the first of its kind focused on these issues. Gaps were noted with countries such as Pakistan, Cameroon, and even Libya (with whom the U.S. and UK have been working for the past 5 years) coming forward to ask for assistance. On the professional responsibility front there are a wealth of ideas but, with some exceptions, there has been less forward movement in this area, perhaps because movement relies more on civil society rather than mandatory government regulations of one kind or another. Various "forcing" events may be required to push this along and Del

recommends Washington give careful thought to what kind of recommendations arising from the December Meeting of States Parties could provide an appropriate nudge.

¶4. (SBU) Overall the meeting was conducted in a professional manner and included the innovation of two "poster sessions", several "panel" discussions and seven early morning/lunchtime events hosted by civil society representatives. If there were any criticism at all, it can be chalked up to being victims of our own success. In their enthusiasm, the Chairman and his ISU team scheduled more guests and presentations than physical time allowed, so the meeting provided little time for follow-up questions and answers. At the same time, the depth and breadth of participation provided a wealth of material on which to draw in moving forward.

¶5. (SBU) The U.S. and its Allies should begin to lay groundwork for productive results at the Meeting of States Parties in December 2008. Further down the road is the 2009 topic on international cooperation, capacity building, and related assistance, a NAM favorite but upon which the West has a good story to tell. The WEOG provides the Chairman for the 2009 meetings; Canadian Amb. Grinius has the support so far of the non-EU members of the WEOG for the job, and we know some EU members have supported him as well, assuming the EU doesn't put forward a candidate. The EU is meeting soon to discuss, after which the Canadian candidacy can be consulted more broadly with a view to a December 2008 decision this matter. Having the WEOG candidate identified early on will provide additional time to prepare for handling this challenging topic. End Summary.

Opening of Meeting; National Statements

¶6. (U) The 2008 Meeting of BWC Experts opened smoothly on August 18, running successfully through the usual housekeeping items: adoption of the agenda, an amended Program of Work, the Rules of Procedure, and participation in the meeting. The Chairman, Ambassador Georgi Avramchev of the Republic of Macedonia, made introductory remarks and pointed to the four information papers provided by the ISU (Biosafety and Biosecurity; Developments in Codes of Conduct Since 2005; Oversight of Science; and Education, Outreach and Raising Awareness).

¶7. (U) Introductory statements were made by many States Parties, including: France for the EU, Cuba for the Non-Aligned Movement, Pakistan, Saudi Arabia, Japan, U.S., Russia, China, ROK, Indonesia, Nigeria, Libya, Iran, Peru, Colombia, Albania, Norway, India, Germany, and Morocco. Key themes included: BWC universalization (and welcoming THE UAE, Cameroon, and Morocco as new States Parties); national implementation; 1540 legislative support; international cooperation; and implementation of BWC's Article X; verification protocol revival (NAM stressed the importance of effective verification, Russia specifically called for resumption of the Ad Hoc Group with its existing mandate); dual-use and bioterrorism threats; and the need to balance biosafety and biosecurity measures while avoiding obstacles to advances in the life sciences, as well as country-specific implementation on codes of conduct. Progress made since consideration of both topics in 2003 and 2005, respectively, was cited, as well requests for assistance from some countries (Sudan, Libya, others). Georgia also made an impassioned intervention on "ethnic cleansing" by Russian troops, noting that Russia has yet to withdraw and requesting assistance; Russia did not rise to the bait, but rather insisted upon the need to stick with the agreed BWC experts agenda, and avoid "artificial politicization". The Chair echoed the Russian request to stay on the agreed expert's agenda. (Note: The Georgian BWC Expert later told US Deloffs that she was under instructions to make that statement. End Note.)

¶8. (U) The World Organization for Animal Health (OIE) and

seven NGO's provided presentations on relevant research and activities in support of the 2008 topics: international measures to improve biosafety and biosecurity, and the development of codes of conduct and educational programs to promote awareness on dual-use issues and the BWC. (See detailed NGO presentations in the NGO Lunch Section.)

"Biosafety and Biosecurity Concepts"

¶ 9. (U) At the August 19 plenary meeting, Cameroon received observer status. Four International Governmental Organizations: the World Health Organization (WHO); the Organization for Economic Cooperation and Development (OECD); the United Nations Environment Program/Global Environment Facility (UNEP/UNEF); and the European Commission (EC) gave presentations. WHO's Dr. Nicoletta Previsani detailed biosecurity efforts aimed at "minimization of deliberate release" and cited the 2001 anthrax letters and the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak in Singapore to stress that even though the event is over the pathogens still remains in one U.S. (USAMRIID) and three Singaporean laboratories. She noted a global increase of biosafety level three (BSL3) labs and commented that Brazil had twelve BSL3 labs. Georgia asked why Brazil needs twelve BSL3 labs. Brazil responded that this wasn't enough and they would be building more BSL3, as well as two new BSL4 (highest containment level) labs. Sudan asked for assistance in drafting relevant scientific/legal texts and train-the-trainer assistance.

¶ 10. (SBU) Following the OECD's presentation on security guidelines for access to dangerous pathogens, Iran asked if there should be mandatory criteria for transfer of bio agents "outside the convention?" OECD noted they have established an approach that can be used for peer review and evaluation for various sensitive projects and agents and their possible transfer. Japan stated that they are "legally obligated to store pathogens in four categories" and could OECD help them categorize their new strain of attenuated Ebola? UNEP spoke to biosafety/security elements of the Cartagena Protocol on Biosafety in relation to living modified organisms and synthetic biology. They have been working with 123 countries to establish biosafety policies; 103 countries are complete.

¶ 11. (U) Returning to the States Parties presentations, South Africa, Argentina, Australia and Germany introduced their national papers. The U.S. outlined assistance given to the WHO and OECD on development of pathogen security guidelines. Of particular note was Canada's overview of recently proposed legislation ("Bill C-54" under the 1994 Human Pathogens and Toxins Act) which will require all people working in BSL3-4 labs to have a security clearance at the SECRET level or above. The UK presented their national paper on the 2007 Foot and Mouth Disease (FMD) outbreak, summarizing the background and future considerations in handling animal pathogens, and emphasizing the similarities of human and animal pathogens. (This is apparently the first time the UK has spoken about FMD in an international meeting, despite great pressure to do so, especially in the bioterrorism context (BTEX). It remains a highly sensitive subject in the UK.) Norway gave an extensive presentation on the EU "Laboratory Biorisk Management Standard" (CWA 15793) and its applicability under the BWC on biosafety/security. They emphasized the similarities across all BSL-levels, despite various circumstances. Denmark noted the significant changes in their legislation, particularly the establishment of the Center for Biosecurity and Biosafety, which provides training for universities, hospitals, research and private organizations; incorporating physical, transportation, information security, material controls and a threat assessment algorithm.

¶ 12. (U) Nigeria focused on the extensive numbers of its indigenous pathogens which underscore Nigeria's need for biosecurity and urgent assistance in establishing a biosecurity program. It has established an Office of

National Authority (ONA) for Chemical and Biological Weapons Conventions implementation and developed a "Code of Conduct and Laboratory Manual" for scientists and is also establishing a "Field Laboratory Program."

¶13. (U) Cuba presented the main elements of its 1990 legal instrument implementing the BWC, emphasizing its ongoing concern about human, animal and plant toxins, especially modified organisms and exotic species. It also mentioned its 1996 legal instrument regarding lab staff members and the integrity of persons regarding property and information security; it is drafting legislation on "information protection" in sensitive labs. Pakistan's presentation on Prevention, Control and Surveillance recognized that there were differing opinions concerning appropriate levels of protection and what constitutes acceptable levels of risk. It is meeting in a number of working groups to address these differences of opinion. It is also organizing a "National Plan of Conduct." Bulgaria spoke of its efforts since 2006. Morocco gave a presentation on the BWC related efforts of the MENA region countries and emphasized their determination to secure life sciences research by ensuring legally binding measures are in place in each country.

¶14. (U) The Industry Panel Discussion had four speakers: Gary Burns (AstraZeneca), John Keddie (GlaxoSmithKline) Robert Friedman (J. Craig Venter Institute) and Shrikumar Suryanarayan (India; Association of Biotechnology Led Enterprises (ABLE). It is significant that representatives from prominent industry attended not only their session but several days of the meeting and made well-informed points comparing their views to what is discussed in government/IGO and NGO forums. The first two speakers represented large pharmaceutical firms that recognize the security concerns but wish to see a risk-based balance. They noted that the pharmaceutical industry has very high Good Manufacturing Process (GMP) standards that are directly related to their risk. They have been involved with Advisory Groups and other studies to ensure their input into the GMP standards, thus they have an interest in meeting the standards they helped to develop. Keddie expressed concern that registration of dual-use equipment would have significant administrative burden. He stressed the need for regulations that are simple and can be applicable across different areas, observing that "local" decisions have global impact. Research and development is global, as is the industry, which needs to be able to move material, biological samples and agents globally. Finally, referring to an earlier question about new delivery technologies that have a legitimate use in medication delivery, he expressed concern that if the research is restricted because of weaponization concerns, the benefits of these new technologies may not be available for medical uses.

¶15. (U) Friedman spoke about the genomics industry, DNA sequencing and the benefits of their synthetic biology program. The panel ended with the note of caution that mechanisms for biosecurity may unduly interfere with research, biosecurity measures should not make daily business more difficult and controls should be proportional in relation to risk. One speaker commented that we are drifting from the original intent of the BWC and becoming focused on biosecurity and synthetic biology. Another comment was that the pharmaceutical industry should not be the focus of concern but rather Do-It-Yourself biology (DIY-Biology).

Capacity-Building

¶16. (U) The August 20 session began with presentation from professional societies. The American Biosafety Association (ABSA) recognized the State Department for support of Former Soviet Union scientists in attending annual ABSA meetings. The Pacific Asia Biosafety Association (P-ABSA) requested regional States to step forward and support, as well as implement their "Biosafety Plan." The European Biosafety Association (EBSA) noted concern that some States have

legislation for biosafety/security that can cause conflicts with organizations who propose biosafety standards. ABSA Canada recommends licensure and security clearances for anyone who accesses BSL-3 or 4 pathogens.

¶17. (U) The IAP, made up of nearly one hundred national science academies, does not have a code of conduct per se, but rather promotes Principles of Awareness ("Scientists have an obligation to do no harm"), Education, Safety and Security, Accountability and Oversight. The International Network of Engineers and Scientists for Global Responsibility (INES) emphasized that the majority of scientists remain unaware of dual-use aspects of their work. They believe that an approach to managing biorisks that is exclusively bottom-up in character will have little chance of success on its own and a top-down method is the right process, i.e. licensing or issuing of permits. Licensure should not only include facilities, but also the work itself and also the principal investigators. There must also be periodic checks of the licensing authority. Brazil commented that this is too optimistic.

¶18. (U) The panel discussion on Risk Management included speakers May Chu and Cathy Roth (WHO), Ian Gillespie (OECD), Keith Hamilton (World Organization for Animal Health (OIE), Paul Huntly (Det Norske Veritas, an accreditation body), Brooke Rogers (Kings College London). Gillespie described Risk Management as a process and presented a "Framework for Governance." He described managing risk as needing a proportionate response to risk; building in the human factor; having standards and best practices but not "recipes." The approach should be to harmonization, but not rigidity, and transparency through certification and accreditation. Keith Hamilton described "Good Risk Management Principles" as being flexible enough to deal with complexities of life with use of the best information available, making reasoned and logical decisions, and being objective (i.e., based on scientific principles.) He said that quantitative and qualitative risk management strategies both have their places. The qualitative approach requires a good understanding of the real world to include & everything⁸ that contributes to the risk. A quantitative approach allows comparisons, can be precise if good data is available, and allows comparisons after interventions but may require complicated modeling skills. The WHO presentation focused on their plans to develop Risk Management Programs.

¶19. (U) The International Center for Genetic Engineering and Biotechnology (ICGEB)(Decio Ripandelli) emphasized the need to improve laboratory skills and facilities in developing nations. The UN 1540 Committee (Olivia Bosch) walked through the basics of UNSCR 1540 noting that implementation involves reporting of legislation and enforcement measures and this reporting is used as the baseline for risk management. She emphasized that national submissions on 1540 support BWC, counterterrorism and larger nonproliferation obligations. Information from each of these areas should be used to complete national submissions. When noting the 1540 staff could now provide direct assistance, based on the May 2008 UNSC Resolution 1820, Japan surprisingly indicated they would ask for assistance with more in-depth penal legislation as did the Philippines. She recommended the CWC National Authorities as a resource for smaller nations meet their BWC and 1540 requirements. The WHO gave a presentation on the WHO public health mandate for biosafety and biosecurity. They referenced WHA 58.29, "Enhancement of Laboratory Biosafety," which discusses the state of laboratories in underdeveloped countries.

¶20. (SBU) Twelve countries (France, the U.S., Japan, Nigeria, UK, Indonesia, Cuba, Australia, Turkey, Malaysia, Argentina, and Sudan) delivered statements on their efforts to improve biosafety and biosecurity measures and on capacity building. Most presentations focused on recent and upcoming workshops and conferences, supportive legislation, and educational programs. The U.S. statement highlighted work with the UK and Libya efforts with the UK and Libya on promoting cooperative implementation of biosafety/biosecurity and

bioethics measures, indicating the plan to table a working paper in December on these efforts. Japan declared its national goal of creating "the world's safest region when it comes to biosafety and security." Indonesia detailed its ongoing efforts to build its first BSL 3 laboratory by describing the challenges it faces with finding the appropriate space, materials and technical know-how to build the laboratory. Malaysia described its 2007 legislation, the "Biological Weapons Bill," which expands controls over transportation, use and quantity of toxics without justification for peaceful use, and related punitive measures. Sudan, noting Art. X (assistance) obligations of all States Parties, indicated it is drafting national legislation in this area, but pointedly called for technical and financial assistance in promoting biosafety/security in its region.

**&Oversight of Science, Education and Awareness-Raising,
Codes of Conduct8**

¶21. (SBU) During the Oversight of Science discussion on August 21, the UK, Australia, Japan, China, Nigeria, Cuba, Turkey, Malaysia, Argentina and Sudan either gave introductions to national papers or said little of interest. France delivered the EU presentation on the "EU Cooperative Initiative to Improve Biosafety and Biosecurity," which was adopted in 2003 to counter the WMD threat. The EU seeks partnership with BWC States to sustain the initiatives. France presented a paper discussing the need to "Use Laboratory Notebooks as a Tool for Traceability of Research Activities" and gave another presentation on "Biosafety Risk Assessment."

¶22. (U) Indonesia made a presentation with Norway on a new BSL-3 Laboratory which the Norwegians designed and built in less than a year. Canada and the Kyrgyz Republic gave a presentation on their cooperation under the 2002 G-8 Kananaskis Statement on WMD and its goal of counterterrorism, particularly on guidelines and standards, training, biosafety accreditation and a new BSL-3 laboratory and repository. A related treaty was signed in August 2008 with ratification expected in a few months.

¶23. (U) Cameroon (see details on accession para) made a presentation discussing their legislative efforts to modify their Constitution to enable their ratification of the 1925 Geneva Protocol and accession to the BWC in the near future. They described their membership in the Biodiversity Convention (Cartagena Protocol).

¶24. (U) The U.S. outlined the activities at the National Science Advisory Board for Biosecurity (NSABB). A question was raised about why the term "life science research" was used in the NSABB's work, rather than "activities in the life sciences" and whether "exploratory development" would be a better term? The U.S. presenter responded that the NSABB had consulted with many organizations as well as industry on the term "life science research" and this term was chosen as most appropriate for describing their work and for its brevity. There was also a question about any interest in regulating genomics and the response was to make clear the NSABB is an advisory panel without the authority to make policy.

¶25. (U) Japan made a presentation based on the experience with Aum Shinrikyo and how Japan approaches the challenges of local terrorism. One concept that came from these challenges was whether a scientist with "low future potential" should be included in a list of possible risk factors. They discussed the dual-use challenge in broad terms, describing types of experiments in advanced technologies. Paradoxically, however, Japan had concluded that the Fink Commission criteria are too inclusive.

¶26. (U) The International Union of Pure and Applied Chemistry (IUPAC) made a presentation emphasizing that education concerning research potential is about choices and scientists

need to make the right choices. The WHO's Cossivi gave a presentation on their Biosecurity Project and a summary of the related Bangkok meeting in December 2007.

¶127. (U) The U.S., UK, Switzerland, France, Pakistan, Cuba, Brazil, Germany, the U.S. National Academy of Sciences (NAS) and the 1540 Committee gave presentations on oversight, education, raising awareness and codes of conduct. The NAS stressed its role in promoting biosecurity through in-depth reports and workshops, and the importance of dialogue between policy makers and scientists. Cuba explained its code of conduct as being dictated by national priorities, where there is national control of research, education and transfers in the bio sector. This was in contrast to Germany's presentation which stated that the Government funds the majority of projects but scientists establish the priorities and control distribution of funds. Germany's current priority is on research for pathogens and toxins. Switzerland distributed a fact sheet used to educate professional associations and academic institutions on the importance of codes and consequences of biological research.

¶128. (U) A discussion panel focused on the importance of education with experts from ICRC (Robin Copeland), UNESCO, International Center for Genetic Engineering and Biotechnology, and the International Council for Life Sciences. The panel expressed a desire for the 2011 RevCon to include education on the agenda by requesting countries to report back on developments on curriculum and training programs.

¶129. (U) Several States Parties (Australia, Argentina, InQ Georgia Q Pakistan) gave presentations Friday morning on education and raising awareness. Of note, India stated that there is national guidance on education and awareness training, but ultimate responsibility to ensure compliance is up to the industries and individual Ministries. Georgia's presentation recognized U.S. efforts, specifically DTRA,s and the \$280M in funds, to help eliminate biological weapons and improve security and surveillance systems for dangerous pathogens in the region.

¶130. (U) The United States, Netherlands, ROK, Sweden, Brazil, Bulgaria, China and Ukraine gave presentations on codes of conduct. The U.S. presentation was well received with the ROK asking how to close the gap between codes and law. Del rep replied that codes apply to all life sciences, but agreed that there are gaps.

¶131. (U) China, when presenting their view on codes of conduct, indicated that violators are to self-report themselves. There was no discussion of efforts of a national authority ensuring the guidance. Ukraine also stressed that code of conduct compliance is up to individual scientists.

Poster Sessions

¶132. (U) "National, Regional and International Measures to Improve Biosafety and Biosecurity." This inaugural poster session consisted of 16 posters from States Parties, professional organizations, and NGO'S on biosafety/security. This innovation was deemed successful with strong attendance and an excellent opportunity for detailed, yet informal, interaction with the mix of attendees. The second poster session, focusing on education, awareness, and codes of conduct, consisted of over a dozen posters and was equally well-attended.

NGO Lunches

Synthetic Biology: Engineering Life Science (Geneva Forum)

¶133. (U) A presentation was given on August 18 on an

educational seminar being developed that is geared towards non-scientific policymakers on the future of biological advances specific to genetic engineering and the dual-use dilemma (that peaceful scientific research may be exploited for malicious use due to universal materials, technology and expertise in the life sciences). They posited that the use of synthetic biology for malicious purposes is quite futuristic, however, the ability of non-scientists to be able to use biology to manufacture genetic material and eventually organisms to advance fields such as alternative energy (biofuels) and environmental remediation is going to be commonplace given the advances in technology.

Dual-Use at the Cutting Edge: What to do about Oversight?

¶134. (U) On August 19, there was an academic panel discussion moderated by Malcolm Dando (University of Bradford). BWC Chairman Avramchev opened the discussion by stating that "the BWC stands ready to ensure biopathogens are used only for good." Panelists included Dr. Alexander Kelle (Bath University), Kathryn Nixdorff (Darmstadt University of Technology), Dr. David Friedman (Israeli Institute for National Security Studies) and Elisa Harris (Center for International Security Studies at Maryland). Nixdorff discussed the Lemon-Relman Committee report in relationship to bioregulators and delivery techniques. She specifically mentioned Advances in Targeted Delivery Techniques for vaccines, cancer therapy, immunotherapy, and viral vectors. She also focused on aerosols in relation to nanoparticles, opiates (Moscow theater incident) and oxytocin (for a false sense of security in humans). Dr Kelle spoke about synthetic biology and the biosecurity implications of this new technology. Dr. Friedman described Israel's proposed new law based on recommendations of the "Commission of Oversight of Biotech Research" which is nearing approval in the Israeli Parliament. Elisa Harris made a general presentation concerning oversight of new technologies. There was also discussion about a new Periodic Table for Biology similar to the Chemical Periodic Table.

BWC Universalization (Bioweapons Prevention Project)

¶135. (U) On August 20, the BWPP roundtable included Kathryn McLaughlin (BWPP), Kathryn Nixdorff (Hamburg), Alan Pearson (Center for Nonproliferation and Arms Control), Gert Harigel (BWPP Board) and Amb. Sergey Batsanov (Pugwash). Prof. Nixdorff made a statement that there should be benchmarks for the BWC and that (How do you increase participation in something (the CBM) that is not mandatory and even if participation in the CBM is not legally binding, it should be politically binding.

International Biosecurity Forum (Interacademy Panel (IAP),
National Academies of Science (NAS))

¶136. (U) On August 20, the Interacademy Panel (IAP) held a roundtable to discuss code of conducts, education and awareness-building. The discussion was lead by Alastair Hay (University of Leeds), Ben Rusak (U.S. NAS) and Sergio Pastrana (IAP). Mr. Hay stressed the importance of improving awareness among scientists concerning misuse of science and securing a culture of responsibility. He endorses development of a code of conduct in the life sciences and urges governments to follow-up on their proposals. Mr. Rusek stated that there should be no limits on research and progress on major research does not have dual-use potential. Individual awareness is critical and there should be a bottom-up voluntary awareness with a top-down oversight. He encourages developing an on-line biosecurity advice portal. Mr. Pastrana emphasized building consensus in the scientific community to promote proper conduct and prevent hindrance of science. He suggested that the UN should lead coordinating

of activities, organizing meetings, improve networking, and deepen connections between the scientific community and policy makers. The audience commented that the IAP should take the lead as they have the breadth of audience; IAP answered that they do not have the mandate or resources to accept this task.

National Implementation Measures for Effective Biosecurity
and Biosafety (VERTIC)

¶37. (U) On August 22, VERTIC, the London-based NGO, briefed on its capabilities to provide services to countries that request assistance in drafting and enacting biological security-related legislation. Also on the podium were UK and Netherlands reps who announced their financial support to allow VERTIC not only to analyze legislation and review draft bills, but also to send experts to capitals. U.S. del rep expressed strong support for VERTIC's efforts and said the U.S. also hopes to be able to provide financial assistance in the near future. He also urged Dels to consider how assistance could be made available for implementation and enforcement of legislation.

End of text of part one of two.

Rocca sends.

STORELLA